MAY 27 2011 K100895

005 510(k) Summary as required by 21CFR807.92(c).

1.0 Submitter:

Name : Dipped Products Limited
Street Address : 400 Deans Road
City : Colombo 10
Country: Sri Lanka
Contact Person: Dr. W.S.E.F. Fernando
Phone No. +94 11 2683964
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Registration Number: 8040667
Date Summary Prepared: 1-4-2010

2.0 Name of the device:

Proprietary or Trade Name: Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30)
Common Name : Patient Examination Gloves, Powder Free (21 CFR 880.6250)
Product Class: I
Device Name: Powder Free Latex Examination Gloves, Non-Sterile
with Protein Content Labeling Claim (50 Micrograms or less)

3.0 Identification of the Predicate Device(s):

Classification Name : Patient Examination Gloves (21 CFR 880.6250)
Product Class: I
Product Code: 8O LYY (Powder Free Latex Examination Gloves, Non Sterile with Protein Content Labeling Claim *(50* Micrograms or less) meets all the requirements of ASTM standard D *3578* – 05 .) for type I gloves

Identification of current legally marketed predicate devices

Manufacturer	**Product Description**
Predicate 1 **WRP** **510(k) Number: K022808**	**Dermagrip Powder Free Latex Examination Gloves**
Predicate 2 **Maytex Corporation** **510(k) Number: K935315**	**Maytex Powder-Free Latex Exam Gloves**

4.0 Description of the Device:

Patient Examination Gloves (21 CFR 880.6250)
Product Class: I
Product Code: 8O LYY (Powder Free Latex Examination Gloves, Non Sterile with Protein Content Labeling Claim *(50* Micrograms or less) meets all the requirements of ASTM standard D *3578* – 05.). The gloves are made of natural latex rubber and are worn on the examiner's hand to prevent contamination between patient and examiner.

5.0 Intended Use of the Device:

Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Technical Characteristics of device compared to the legally marketed predicate devices

Dimension Characteristics :

Sample Ref	**thickness (mm)**		**Palm width (mm)**					**Length (mm)**
	Finger	palm	**size**					
			XS	S	M	L	XL	
Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30)	0.37 ±0.03	0.30 min	77	85	95	110	118	300 min
WRP 510(k) K022808	0.40	0.30	79	84	96	105	117	292
Maytex 510(k) K935315	*0.40-0.46*	*0.38-0.44*	N/S	N/S	98-103	103-110	111-117	*300 min*
ASTM D3578-05	*0.08 min*	*0.08 min*	*70 ±10*	*80 ±10*	*95 ± 10*	*111± 10 mm*	*N/S*	*220/230 min*

Performance Characteristics (Mechanical Performance, Extractable Protein Content :

Sample Ref	Tensile strength (MPa)		Elongation at break (Percebnt)		EP content
	unaged	Aged (70C/166hrs)	unaged	Aged (70C/166hrs)	
Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30)	21 min	16 min	750 min	600 min	50µg/g or less
WRP 510(k) K022808	29	26	900	860	50µg/g or less
Maytex 510(k) K935315	14 min	14 min	500 min	500 min	Less than 100µg/g of glove
ASTM D3578-05	*18 min*	*14 min*	*650 min*	*500 min*	*200* µg */dm²*

NOTE: The term "min" refers to "minimum" in these tables.

7.0 Substantial Equivalence Based on Assessment of Clinical Performance Data:

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

8.0 Conclusions:

The subject device has the same intended use and similar characteristics as the predicate device(s). Technical characteristics and performance of the subject device are comparable to those of the predicate device(s). Therefore no new questions of safety or effectiveness due to performance are raised. Similarly, biocompatibility documentation demonstrates that materials used to fabricate the subject device do not raise any new questions of safety or effectiveness. Thus, the Dipped Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30) is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dipped Products Limited
C/O Mr. Bhavesh V. Sheth
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAY 27 2011

Re: K100895
Trade/Device Name: Palm Pro X –Powder Free Latex Examination Gloves (6PF2G30)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: May 13, 2011
Received: May 16, 2011

Dear Mr. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number : K100895

Device Name: Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30).

Indications for Use:

Palm Pro X - Powder Free Latex Examination Gloves (6PF2G30) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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